

K153463 CD HORIZON Spinal System, IPC POWEREASE System

Dec 30, 2015
29 days to decision

K153463 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k153463/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 1, 2015
Decision date	Dec 30, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Becky Ronner
510(k) history	170 submissions · 159 cleared · 2000-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k153463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026